

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

The effect of oral melatonin supplementation on the number and quality of oocytes and embryos in infertile women with endometriosis and undergoing intracytoplasmic sperm insemination

Protocol summary

Study aim

The effect of oral melatonin supplementation on the number and quality of oocytes and embryos in infertile women with endometriosis undergoing intracytoplasmic sperm insemination (ICSI)

Design

Randomized controlled trial with 2 parallel groups, triple blind, on 100 patients with endometriosis will be performed. The randomized block allocation method will be applied.

Settings and conduct

Data collection tools are patients records ,checklist. The checklist includes demographic and clinical information index that is completed during treatment cycles. Before and after the intervention, a vaginal ultrasound is performed by a gynecologist and the size of the endometrioma is recorded. Melatonin 5 mg and placebo are prescribed according to codes A and B. Patients, outcome assessors and Statistical analyzer are unaware of the allocation process.

Participants/Inclusion and exclusion criteria

Inclusion criteria are infertile women aged 20 to 40, under ART treatment along with a laparoscopy or ultrasound report indicating the presence of endometriosis in the file. Exclusion criteria: premature ovarian failure, severe male factor (according to WHO criteria, sperm count less than 15 million per milliliter and motility less than 50% and normal morphology less than 4%, occurrence of complications and drug sensitivity such as (fatigue, headache, blurred vision, nausea, diarrhea), diagnosis of adenomyosis, chronic diseases including thyroid, adrenal diabetes and current malignancy or history of malignancy, uterine myoma and PID, patients whose infertility is due to obstruction problems, genetic problems or hormonal problems.

Intervention groups

Group A includes patients receiving melatonin and group

B includes patients receiving placebo.

Main outcome variables

Oocyte number and quality, embryo number and quality and fertilization rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171209037794N5**

Registration date: **2023-10-01, 1402/07/09**

Registration timing: **prospective**

Last update: **2023-10-01, 1402/07/09**

Update count: **0**

Registration date

2023-10-01, 1402/07/09

Registrant information

Name

Parvaneh Mirabi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 8898 7958

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-02, 1402/07/10

Expected recruitment end date

2024-03-02, 1402/12/12

Actual recruitment start date

empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of oral melatonin supplementation on the number and quality of oocytes and embryos in infertile women with endometriosis and undergoing intracytoplasmic sperm insemination

Public title
The effect of oral melatonin supplementation on the number and quality of oocytes and embryos in infertile women with endometriosis

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Infertile women 20 to 40 years old under ART treatment along with laparoscopy or ultrasound report indicating the presence of endometriosis

Exclusion criteria:
Premature ovarian failure. severe male factor according to the criteria (WHO), sperm count less than 15 million per milliliter and motility less than 50% and normal morphology less than 4%. Occurrence of complications and drug sensitivity such as (fatigue, headache, blurred vision, nausea, diarrhea). Diagnosis of adenomyosis and chronic diseases including thyroid, adrenal diabetes, current malignancy or history of malignancy, uterine myoma and PID . Patients whose infertility is due to obstruction problems, genetic problems or hormonal problems.

Age
From **20 years** old to **40 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
The randomized block allocation method will be applied. The number of considered blocks is 4. Randomization will be done using a dedicated online randomization software (<http://www.randomization.com>). The allocation sequence is password protected and accessible only to an independent investigator not involved in the study.

Blinding (investigator's opinion)
Triple blinded

Blinding description
The drug and placebo, which have the same size, color,

taste, and smell, are provided to both groups in completely similar containers based on random allocation by the design partner. Therefore, none of the patients are aware of the assigned treatment and will not be informed until the end of the study. Also, the researcher evaluating the intended outcomes is unaware of the random allocation process and the type of treatment performed. In order to analyze the data, a statistician who is separate from the study process and is unaware of all the processes will be used.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Babol University of Medical Sciences

Street address

Babol University of Medical Sciences- Ganj Afrooz street.

City

Babol

Province

Mazandaran

Postal code

4717647745

Approval date

2023-09-17, 1402/06/26

Ethics committee reference number

IR.MUBABOL.HRI.REC.1402.093

Health conditions studied

1

Description of health condition studied

Endometriosis

ICD-10 code

N80

ICD-10 code description

Endometriosis

Primary outcomes

1

Description

Number and quality of embryos

Timepoint

24 hours after ICSI

Method of measurement

Microscopic assay

Secondary outcomes

1

Description

The number and quality of oocytes

Timepoint

oocyte pick up day

Method of measurement

Microscopic Assay

2

Description

Fertilization rate

Timepoint

24 hours after ICSI

Method of measurement

Microscopic Assay

Intervention groups

1

Description

Intervention group: patients will receive 5 mg melatonin tablet (Jalinous Pharmaceutical Company), one hour before sleep, once a day for 2 months.

Category

Treatment - Drugs

2

Description

Control group: patients will receive placebo (Jalinous Pharmaceutical Company) once a day for 2 months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemezahra infertility center

Full name of responsible person

Parvaneh Mirabi

Street address

Fatima Al-Zahra Fertility and Infertility Specialized Treatment Center, old Amol-Babol road, Babol, after Mohammad Hasan Khan bridge

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Dr. Mehdi Rajabnia

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Babol University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Parvaneh Mirabi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Infertility and Reproductive Health

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

-

When the data will become available and for how long

-

To whom data/document is available

-

Under which criteria data/document could be used

-

From where data/document is obtainable

-

What processes are involved for a request to access data/document

-

Comments